Amendment No. 1 to HB0677

Kumar
Signature of Sponsor

AMEND Senate Bill No. 1310 House Bill No. 677*

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, is amended by adding the following as a new part:

56-7-3501. Part definitions.

As used in this part:

(1) "Health benefit plan" has the same meaning as defined in § 56-61-102;

(2) "Health carrier" has the same meaning as defined in § 56-61-102;

(3) "Healthcare provider" has the same meaning as defined in § 56-61-102;

(4) "Interchangeable biological product" means a biological product licensed by the federal food and drug administration and determined to meet the safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4);

(5) "Pharmaceutical sample" means a unit of a prescription drug that is not intended to be sold;

(6) "Prescription drug" means a drug that under federal or state law is required to be dispensed only pursuant to a prescription order or is restricted to use by individuals authorized by law to prescribe drugs;

(7) "Required prescription drug" means a medication that is required as part of a step therapy protocol;

(8) "Step therapy exception" occurs when a step therapy protocol is overridden in favor of immediate coverage of the healthcare provider's selected prescription drug;

(9) "Step therapy protocol" means a protocol, policy, or program that establishes a specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular patient, are covered by a health carrier or health benefit plan; and

(10) "Utilization review organization" means an entity that conducts utilization review, as defined in § 56-6-703, other than a health carrier or health benefit plan performing utilization review for its own health plans.

56-7-3502. Exception process.

(a) If a health carrier, health benefit plan, or utilization review organization denies coverage of a prescription drug for the treatment of a medical condition through the use of a step therapy protocol, then the health carrier, health benefit plan, or utilization review organization must provide access to a clear, readily accessible, and convenient process for a patient or prescribing practitioner to request a step therapy exception. The process must be easily accessible on the website of the health carrier, health benefit plan, or utilization review organization. A health carrier, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this subsection (a).

(b) A health carrier, health benefit plan, or utilization review organization shall grant a step therapy exception if:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction by, or physical or mental harm to, the patient due to a documented adverse event with a previous use of the required prescription drug or a documented medical condition, including a comorbid condition;

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

(3) The patient, while under the current or a previous health insurance or health benefit plan, has previously tried the required prescription drug or another drug with the same mechanism of action as the required drug and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) The required prescription drug is not in the best interest of the patient, based on clinical appropriateness, because the patient's use of the drug is expected to:

(A) Cause a significant barrier to the patient's adherence to or compliance with the patient's plan of care;

(B) Worsen a comorbid condition of the patient; or

(C) Decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; or

(5) The patient is currently receiving a positive therapeutic outcome on a prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan, and the patient's healthcare provider gives documentation to the health insurance, health benefit plan, or utilization review organization that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the patient based on the known characteristics of the specific enrollee and the known characteristics of the required prescription drug.

(c) Upon granting a step therapy exception, the health carrier, health benefit plan, or utilization review organization shall authorize coverage for the prescription drug

prescribed by the patient's treating healthcare provider if the prescription drug is covered under the current health insurance, health benefit plan, or utilization review organization.

(d) The health carrier, health benefit plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within the turnaround times established pursuant to § 56-6-705 for an expedited appeal. If a response by a health carrier, health benefit plan, or utilization review organization is not received within that time period, then the exception is granted.

(e) A step therapy exception is eligible for appeal by an insured.

(f) This section does not prevent:

(1) A health carrier, health benefit plan, or utilization review organization from requiring a patient to try an AB-rated generic equivalent or interchangeable biological product prior to providing coverage for the equivalent branded prescription drug;

(2) A health carrier, health benefit plan, or utilization review organization from requiring a pharmacist to substitute a prescription drug consistent with the laws of this state; or

(3) A healthcare provider from prescribing a prescription drug that is determined to be medically appropriate.

(g) The use of pharmaceutical samples of a required prescription drug is not considered a trial of the required prescription drug as part of a step therapy protocol.

56-7-3503. Rulemaking.

The commissioner of commerce and insurance shall promulgate rules to effectuate this part. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

56-7-3504. Applicability.

(a) This part applies to a group health benefit plan or health insurance coverage offered in connection with a group health benefit plan that provides coverage for a

prescription drug pursuant to a policy that meets the definition of a step therapy protocol, regardless of whether the policy is described as a step therapy protocol, and includes a state or local insurance program, under title 8, chapter 27.

(b) This part does not apply to:

(1) The TennCare program provided for in title 71, chapter 5, or a successor program;

(2) The CoverKids Act of 2006, compiled in title 71, chapter 3, part 11; or

(3) The Access Tennessee Act of 2006, compiled in chapter 7, part 29 of this title.

SECTION 2. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 3. For the purpose of promulgating rules, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect January 1, 2023, the public welfare requiring it, and applies to agreements for health insurance or health benefit plans issued, delivered, entered into, amended, or renewed on or after that date.